PATENTS
Attorney Docket No. 25846-0003
FORMAL COMMUNICATION

CERTIFICATE OF FACSIMILE TRANSMISSION

I hereby certify that this paper is being transmitted by facsimile to the US PTO at fax number 703-872-9306 on February 6, 2003.

Derek P. Freyberg, Reg. No. 29,250 — 2/6/03 Date

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

#14
1614
2-2003

In re Application of:

Elfi Beidermann et al. : Confirmation No.: 7777

App. No.: 09/693,558 : Art Unit: 1614

Filed: October 20, 2000 : Examiner: Phyllis G. Spivack

For: Use of vitamin PP compounds

Commissioner for Patents
Washington, D.C. 20231

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Sir:

RESPONSE TO OFFICE ACTION

In response to the Office Action (restriction requirement) mailed January 6, 2003, Applicants elect for examination the invention of Group I, claims 32-40 and 50; and further elect for examination the species where:

(1) the compound having vitamin PP activity or prodrug thereof is nicotinamide, a compound [*see* claim 32, for example] of formula V where b is 1, and R^{21}, R^{22}, R^{23}, R^{26}, and R^{27} are all hydrogen; and

(2) the compound of formula I is N-[4-(1-benzoylpiperidin-4-yl)-butyl]-3-(pyridin-3-yl)-acrylamide, a compound [*see* claim 38, for example] where each of R^{10}, R^{20}, R^{30}, and R^{40} is hydrogen, k is 0, A^0 is -CH=CH-, D^0 is $-(CH_2)_4-$, E is piperidin-4-yl, and G is 1-benzoyl.

Claims readable on the elected species are claims 32-36, 38-40, and 50.

The restriction requirement is respectfully traversed, however:

The compound having vitamin PP activity is defined both generically in claim 32 and subgenerically by Markush group in claim 33; and the compound of formula I is defined by Markush group in claim 38.

With respect to the restriction requirement between Groups I - IV, to the method claims, these compounds have been restricted into four groups, depending on the substituents; but Applicants note that, for example, the compounds having vitamin PP activity of Group II are simply heterocyclyl ethers

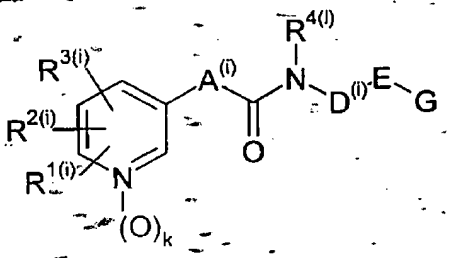
of the compounds of formulae (II), (IIa), and (IIb) where the homocyclyl ethers are classified in Group I, and the compounds of Group III are simply sugar ethers of the compounds of formulae (II), (IIa), and (IIb) where the non-sugar ethers are classified in Group I [and yet the sugars are simply a special case of the "tri-, tetra-, penta-, and hexavalent linear, branched, and cyclic alcohols with 3 to 10 carbon atoms" of claim 33]. Further, claims 32 and 33 at least are **linking claims** with respect to the compounds having vitamin PP activity.

As set forth in MPEP 803.02, second paragraph,

> Since the decisions in Since the decisions in *In re Weber*, 580 F.2d 455, 198 USPQ 328 (CCPA 1978) and *In re Haas*, 580 F.2d 461, 198 USPQ 334 (CCPA 1978), it is improper for the Office to refuse to examine that which applicants regard as their invention, unless the subject matter in a claim lacks unity of invention. *In re Harnish*, 631 F.2d 716, 206 USPQ 300 (CCPA 1980); and *Ex parte Hozumi*, 3 USPQ2d 1059 (Bd. Pat. App. & Int. 1984). Broadly, unity of invention exists where compounds included within a Markush group (1) share a common utility and (2) share a substantial structural feature disclosed as being essential to that utility.

The compounds having vitamin PP activity clearly share a common utility (the vitamin PP activity itself), and share a substantial common feature disclosed as being essential to that activity (all the compounds are based on a 3-pyridyl nucleus and are 3-pyridylmethanols or their ethers, 3-pyridylcarboxylates [nicotinic acids], or 3-pyridylcarboxamides [nicotinamides], and their N-oxide or quaternary ammonium derivatives.

Although the Examiner has not made a restriction requirement between the various compounds of formula I, instead asking only for an election of species, Applicants point out that the compounds of formula I also share a common activity (they are disclosed as cancerostatic or immunosuppressive agents), and share a substantial common feature disclosed as being essential to that activity (all the compounds are of the formula



(I)

as defined in claim 38.

Accordingly, Applicants submit that the restriction requirement, so phrased, is improper and should be withdrawn. Furthermore, the Examiner has made no showing of the necessity for restriction (i.e. undue burden), merely an assertion, and the restriction requirement is improper for that reason also.

Applicants agree, however, that the Examiner may require a provisional election of a single species for examination on the merits to be given effect if the generic or Markush claims are found not allowable, and the election made at the beginning of that section is that election.

With respect to the restriction requirement between Groups I - IV and V, method claims and composition claims, Applicants respectfully submit that the compositions of Group V are linked to the method claims by their activity, and respectfully request that, should the method claims be narrowed during examination so that there will be composition claims of a compound scope as great as the scope of the then-examined method claims, that composition claims then be examined with method claims

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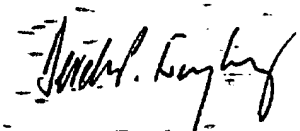
since the search for the compositions and methods is likely to be co-extensive so that no additional effort on the part of the Office will be required.

Respectfully submitted,



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Sir:

TRANSMITTAL

Transmitted herewith for filing in the above-entitled patent application are the following:
Response to Office Action (totaling, with this Transmittal, 4 pages).

No fee is believed due for this response. Please charge any fees that may be required, to Deposit Account No. 08-1641, referring to 25846-0003.

Respectfully submitted,

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